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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,704	06/06/2000	ASHLEY I. BUSH	0609.4350001	2953

7590 11/12/2003

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/380,704	BUSH ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

--The MAILING DATE of this communication appears n the cover sheet with the c rrespond nc address --

THE REPLY FILED 17 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *17 October 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowable: *53*.

Claim(s) objected to: _____.

Claim(s) rejected: *1-2 and 37*.

Claim(s) withdrawn from consideration: _____.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☒ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). *10/17/03, 5/9/03*.

10.☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): The objection to claim 38 is withdrawn in view of the cancelled claim. The rejection of claims 1-2 under 35 U.S.C. § 112, second paragraph are withdrawn in view of the amended claims. The rejection of claim 37 under 35 U.S.C. § 103(a) is withdrawn in view of the amended claim..

Continuation of 5. does NOT place the application in condition for allowance because: Claims 1-2 and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The basis for this rejection is set forth at pages 4-11 of the previous Office Action (22 May 2003).

Applicant asserts that the in vitro results presented in the specification, showing that bathocuprione is able to solubilize amyloid beta in human brain preparations, strongly suggests that bathocuprione would exert similar effects to subjects suffering from amyloidosis. Applicant argues that there has been no evidence presented to explain why the in vitro results are not indicative of in vivo results. Applicant also contends that the Examiner has not presented any evidence or scientifically sound reasoning to indicate that the success obtained with clioquinol would not have also been achieved with bathocuprione. Specifically, no substantially new arguments regarding this issue have been presented, and thus the rejections are maintained for reasons of record. It is noted however, that the Examiner cited Fonte et al., Cuajungco et al., Gnjec et al., and Gillmore in the previous Office Action to indicate the unpredicatability of the state of the art at the time the invention was made. Bathocuprione may have different physiological effects after administration in vivo than the effects observed in vitro. Bathocuprione may also have different effects in vivo than other metal chelators. One skilled in the art cannot predict that all metal chelators will have the same results after administration to a subject. Furthermore, there is no guidance in the specification to indicate that bathocuprione is able to cross the blood-brain barrier and solubilize amyloid beta/treat amyloidosis.